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DATE MAILED: 07/26/2006

APPLICATION NO.	FILING DATE	. FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,626	10/08/2003	Karl R. Leinsing	ONUX-34	7398
23628 7	23628 7590 07/26/2006		EXAMINER	
	ENFIELD & SACKS,	TYSON, MELANIE RUANO		
FEDERAL RESERVE PLAZA 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			ART UNIT	PAPER NUMBER
			3731	

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)				
Office Action Summer	10/681,626	LEINSING, KARL R.				
Office Action Summary	Examiner	Art Unit				
	Melanie Tyson	3731				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 08 Oc	Responsive to communication(s) filed on 08 October 2003.					
3) Since this application is in condition for allowar	☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under E	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4) Claim(s) 1-14 is/are pending in the application.						
4a) Of the above claim(s) is/are withdraw	4a) Of the above claim(s) is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6) Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.	· · · · · · · · · · · · · · · · · · ·					
8) Claim(s) <u>1-14</u> are subject to restriction and/or e	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examine	r.					
10) The drawing(s) filed on is/are: a) acce	epted or b) \square objected to by the E	Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correct	on is required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).				
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.						
See the attached detailed Since action for a list	or the definited depicts net rederve	u .				
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da 5) Notice of Informal P	ate atent Application (PTO-152)				
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	6) Other:					

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DETAILED ACTION

Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - Claims 1-5, drawn to a surgical fastener, classified in class 606, subclass
 151.
 - II. Claims 6-9, drawn to a surgical fastener delivery system, classified in class 606, subclass 142.
 - III. Claims 10-14, drawn to a method for inserting a surgical fastener, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process. For example, instead of being placed in a restraining device and deployed to press a plurality of layers of material together, the surgical fastener could be used by itself to engage a polyp inside an intestinal wall.
- 3. Inventions II and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP §

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806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process. For example, instead of advancing a restraining device through layers of material, the restraining device could be inserted through a patient's mouth, to the bowel wall, to release the fastener over a polyp.

- 4. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.
- 5. If applicant elects the apparatus claims (Inventions I and II), this application contains claims directed to the following patentably distinct species of the claimed inventions:

Invention I:

- Species I depicted in Figures 1A-1C, a surgical fastener having the body of an extension spring.
- II. Species II depicted in Figures 2-3, a surgical fastener where the lower coil forms a half circle.
- III. Species III depicted in Figure 4, a surgical fastener having symmetrical coils.

Invention II:

- Species I depicted in Figures 5A-5F, a deployment device having a swinging stop.
- II. Species II depicted in Figures 6A-6F, a deployment device having a rotatable head.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from Invention I and a single disclosed species from Invention II for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirements be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 7:30 a.m. - 5:00 p.m., alternate Fridays 7:30 a.m. - 4:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson MJ July 17, 2006

ANHTUANT. NGUYEN
SUPERVISORY PATENT EXAMINER
7/17/86